Remarks/Arguments

The foregoing amendments to the claims are of formal nature, and do not add new matter. Claims 119, 139-145 have been canceled without prejudice or disclaimer to claim their subject matter in subsequent continuation or divisional applications. Accordingly, Claims 120-126, 129-131 and 135-138 are now pending in this application.

Claims 124-126, 129-131 and 135-138 have been indicated as allowable. Solely to expedite prosecution in this case, claims 120-123 have been amended with the recitation "wherein the polypeptide encoded by said nucleic acid induces chondrocyte redifferentiation," support for which is found in Example 159, page 530 of the instant specification. The rejections to the presently pending claims are respectfully traversed.

Priority

Applicants submit that they rely on the "chondrocyte redifferentiation assay" for patentable utility of this case which was first disclosed in International Application PCT/US00/08439, filed March 30, 2000, priority to which has been claimed in this application. Based on the disclosure of SEQ ID NO: 118, Figure 69 and PRO943 in Application PCT/US00/08439, Applicants believe that the application provides adequate support and that meets the requirements of 35 USC § 101 and 112, first paragraph. Hence, Applicants should be entitled to at least an effective filing date of **March 30, 2000.**

Claim Rejections – 35 USC § 112, first paragraph- enablement

Claims 119-123 are rejected under 35 U.S.C. §112, first paragraph allegedly because "the specification, while being enabling for the full length nucleic acid of SEQ ID NO: 118, it does not reasonably provide enablement for nucleic acids having at least 80-99% identity to the nucleic acid encoding the polypeptides of SEQ ID NO: 119 or the nucleic acid of the sequence of SEQ ID NO: 118. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims". For the reasons outlined below, Applicants respectfully disagree.

As discussed under the section on "priority", Applicants rely on the chondrocyte redifferentiation assay for patentable utility for the PRO943 protein. This is a well-established

assay and based on the detailed description of the cloning and expression of variants of PRO943 in the specification, and the knowledge of one skilled in the art, Applicants submit that at the time the invention was made one of skill in the art would have known how to prepare nucleic acids with 85-99% identity to the nucleic acids encoding polypeptide of SEQ ID NO: 119 or nucleic acids having at least 80-99% identity to the sequence of SEQ ID NO: 118, since methods for making mutants were routine in the art. The positions at which the mutations occur are irrelevant, so long as the mutants obtained test positive in the chondrocyte redifferentiation assay. The presently pending claims only encompass those nucleic acids that encode polypeptides that test positive in the chondrocyte redifferentiation assay. Such variants can be identified in assays which were well known in the art at the relevant time frame, without undue experimentation. Thus, the claims currently pending are fully enabled, and Applicants request that the present 35 U.S.C. §112, first paragraph rejections to the pending claims be withdrawn.

Claim Rejections – 35 USC § 112, first paragraph- written description

Claims 119-123 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement. The Examiner asserts that the claims are drawn to nucleic acids at least 80-99% identical to SEQ ID NO:119 and thus are genus claims. The Examiner further asserts that the specification does not indicate what distinguishing attributes are shared by the member of the genus. Applicants respectfully traverse this rejection to the pending claims.

The Legal standard for Written Description

The well-established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *In re* Kaslow, 707 F.2d 1366, 1375, 212 USPQ 1089, 1096 (Fed. Cir. 1983); see also Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. see e.g.Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the

amount of knowledge imparted to those skilled in the art by the disclosure. Union Oil v. Atlantic Richfield Co., 208 F. 3d 989, 996 (Fed. Cir. 2000).

Arguments

The instant invention, as currently claimed, is directed to nucleic acids having 90%, 95% or 99% sequence identity with the sequence of SEQ ID NO: 118 and encoding a polypeptide that induces chondrocyte redifferentiation. Thus, the pending claims are now drawn to a genus of polypeptides defined both by structural and functional features, and only those nucleic acids encoding polypeptides that test positive in the chondrocyte redifferentiation assay are encompassed by these claims.

The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of ordinary skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of such highly skilled artisan as of the date the invention was made. In view of Applicant's possession of the PRO943 sequence (SEQ ID NO: 119) and the nucleic acid sequence of SEQ ID NO: 118, and the requirement in the claims that the encoded polypeptide induce chondrocyte proliferation, one skilled in the art at the effective filing date of this application would have reasonably concluded that Applicants were in the possession of the invention currently claimed. Indeed, according to well established case law, such as *The Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the written description requirement for a genus can be met by disclosing a representative number of species within the genus coupled with functional characteristics unifying the genus. The combination of structural and functional features recited in the claims as currently amended, meets this legal standard.

Hence, Applicants request that the present rejection to the present claims be reconsidered and withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641**, referencing Attorney's Docket No. **39780-2730 P1C51**. Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: January 5, 2004

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